SPECIALTY LABORATORIES
27027 Tourney Road 800•421•7110
Valencia, CA 91355 www.specialtylabs.com

August, 2005

Dear Colleague:

New Tests and Reintroductions

We have introduced a number of new tests in this letter including several molecular-based tests:

- Celiac Disease GenotypR™ to detect HLA DQ2 and DQ8, which are strongly associated with celiac disease
- Connexin 26 GenotypR™ to aid in the diagnosis of congenital non-syndromic sensorineural hearing loss
- HLA-B*27 GenotypR™ to aid in the assessment of ankylosing spondylitis or related spondyloarthropathies

We are now offering the most comprehensive assays for confirmation of opiates in the urine of those who are screen-positive on an immunoassay screening test (defined as 300 ng/mL or higher). The comprehensive panels are used to confirm levels as low as 100 ng/mL for Codeine, Dihydrocodeine, Ethylmorphine, Hydrocodone, Hydromorphone, Morphine, Norodeine, Normorphine and Oxycodone.

- Comprehensive panel with 6-Monoacetylmorphine (6-MAM) [6-MAM levels are confirmed as low as 4 ng/mL]
- Comprehensive panel without 6-Monoacetylmorphine (6-MAM)
- A limited panel for Morphine and Codeine only
- Hydrocodone (with Hydromorphone)
- Individual tests for 6-MAM and Hydromorphone

Also available this month are new tests for:

- Free Testosterone by dialysis (includes Free and Total Testosterone) with pediatric reference ranges
- Diagnosis of porphyrias using precise, quantitative HPLC –- and including Coproporphyrin I and III not found in other panels
- S-100 B assays (on serum and CSF) for assessing brain damage in trauma patients or for use as a serum tumor marker
- Bladder cancer that detects bladder tumor antigen in urine

We have developed an improved serum Alpha-1-Antitrypsin PhenotypR™ that includes total serum Alpha-1-Antitrypsin and the phenotype. A comprehensive autoantibody panel -- Myasthenia Gravis Evaluation PLUS -- is also available now for assessing patients with symptoms of myasthenia gravis.

Nichols Institute Diagnostics Kit Delays

Nichols Institute Diagnostics has placed a temporary hold on a number of their diagnostic products as part of a new quality initiative due to ongoing issues with the FDA. Their bulletin (Customer Bulletin No. CB-05-20) indicates that there will be delays in supplying clients with reagent kits. The bulletin also says: “We cannot speculate at this time how long the review process may take or when any particular product will become available.” The products that are in use at this time are in no way problematic, and none have presented with quality issues. *Specialty* already offers a number of these tests using reagents/kits not issued by Nichols. *Specialty* is changing vendors for other kits to avoid a test delay once we run out of the kit. We are currently validating these new assays and anticipate having them completed shortly. See your representative or visit the *Specialty* Web site (www.specialtylabs.com) for a list of tests affected by Nichols’ product hold.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Services at 800-421-4449.

Michael C. Dugan, M.D.
Vice President and Laboratory Director

New from *Specialty*

Effective Tuesday, August 16, 2005 or as noted

1614 Alpha-1-Antitrypsin PhenotypR™

(effective 08/16/05; replaces test code 1514)

Component	Method	Reference Range	Units
A1AT Phenotype	IEF	Phenotype MM	
Alpha-1-Antitrypsin	NEPH	90-220	mg/dL

Specimen/Stability: 1.0 (0.5) mL Serum
Ambient 7 days; Refrigerated 7 days; Frozen 2 months

Clinical Utility: Definitive analysis of hereditary alpha-1- antitrypsin deficiency, which is associated with pulmonary emphysema, hepatoma and chronic hepatitis. Phenotypes MS and MZ are found in about 10% of Caucasians and are associated with mild to moderate reduction of alpha-1-antitrypsin concentrations. MS and MZ phenotypes are increased in rheumatoid arthritis and chronic or recurrent anterior uveitis. The ZZ phenotype is associated with alpha-1-antitrypsin deficiency and predisposes children to early development of emphysema and liver cirrhosis. In adults, the MZ phenotype is associated with hepatoma and chronic hepatitis. Pi typing is a useful test to confirm diagnosis of alpha-1-antitrypsin deficiency.

Schedule: Wednesday and Friday

Turnaround Time: 2-7 days

CPT Code: 82104, 82103

9617U Bladder Tumor Antigen DetectR™

(effective 07/27/05)

Component	Method	Reference Range	Units
Bladder Tumor Antigen	IA	Not Detected	

Specimen/Stability: 2.0 (1.0) mL Urine
Ambient 48hr; Refrigerated 7 days; Frozen 2 months

Collection Instructions: Voided or catheterized urine only. Use a clean urine cup without preservatives or fixatives. Do not use paper or foam cups. Do NOT use first morning urine void. Allow ample time after trauma (surgery, biopsy, etc.) for recovery before collecting sample.

Clinical Utility: Detection of bladder tumor antigen (BTA) in urine -- for evaluating patients with suspected bladder cancer or recurrent bladder cancer. The presence or absence of is not an absolute indicator of transitional cell cancer of the bladder. BTA in urine may also occur as a result of trauma to the bladder. Urinary tract infections or renal/bladder calculi can result in false-positive results. Schedule Sunday - Saturday

Turnaround Time: 1-5 days

CPT Code: 86294

1078 Celiac Disease GenotypR™

(effective 08/16/05)

Component	Method	Reference Range	Units
Celiac Disease Genotype	INNO-LiPA/rSSO	By report	

Specimen/Stability: 5.0 (3.0) mL EDTA Whole Blood
Ambient 72 hrs; Refrigerated 72 hrs

Clinical Utility: Celiac disease is strongly associated with HLA molecules DQ2 (encoded by DQA1*0501 or DQA1*0505 along with DQB1*0201 or DQB1*0202) and DQ8 (encoded in part by DQB1*0302). DQ2 is found in over 90% of patients with celiac disease in comparison to 20-30% of the general population; 5-10% of Celiac patients have HLA-DQ8. Celiac disease is a gluten-sensitive enteropathy that can cause a wide spectrum of clinical symptoms in children and adults. Classical symptoms include arthralgias, diarrhea, abdominal pain, fatigue, bloating, weight loss, growth retardation (in children) and malnutrition resulting from malabsorption of proteins, muscle weakness, edema, malabsorption of vitamins D and A and hypocalcemia.

Schedule: Friday

Turnaround Time: 3-11 days

CPT Code: 83891, 83894x2, 83896x5, 83901x2, 83912

7230 Connexin 26 GenotypR™
(effective 08/16/05)

Component	Method	Reference Range	Units
Connexin 26 Genotype	Invader	By report	
Specimen/Stability	5.0 (3.0) mL EDTA Whole Blood Ambient 72 hours; Refrigerated 72 hours		
Clinical Utility	Test detects the most common Connexin 26 mutations in the GJB2 gene (35delG and 167delT). Up to 50% of prelingual, recessive, non-syndromic deafness can be attributed to mutations in GJB2. Although a broad spectrum of recessive deafness mutations in the GJB2 gene is known, the 35delG mutation is very frequent in populations of European origin (2-3%) while the 167delt mutation is found in the Ashkenazi Jewish population with a frequency of 5%.		
Schedule	Tuesday		
Turnaround Time	3-11 days		
CPT Code	83891, 83892x4, 83896x10, 83903x2, 83912		

1364 HLA-B*27 GenotypR™
(effective 08/16/05)

Component	Method	Reference Range	Units
HLA-B*27	INNO-LiPA/rSSO	By report	
Specimen/Stability	5.0 (3.0) mL EDTA Whole Blood Ambient 72 hours; Refrigerated 72 hours		
Clinical Utility	The presence of HLA-B*27 allele, in conjunction with appropriate clinical symptoms, is consistent with a diagnosis of ankylosing spondylitis (AS) or related spondyloarthropathies. Other autoimmune disorders that have an association with the presence of HLA-B*27 are juvenile rheumatoid arthritis (80% of patients) and Reiter's syndrome (reactive arthritis; 50-80% of patients). HLA-B*27 is also present in 50% of patients with inflammatory bowel disease with spondylitis and psoriasis vulgaris with spondylitis.		
Schedule	Friday		
Turnaround Time	3-11 days		
CPT Code	83891, 83894, 83896x25, 83901, 83912		

4490UR Hydrocodone Urine AccuQuant® (including Hydromorphone)
(effective 08/16/05)

Component	Method	Reference Range	Units
Hydrocodone Urine	LC/MS-MS	<100	ng/mL
Hydromorphone Urine	LC/MS-MS	<100	ng/mL
Specimen/Stability	10.0 (5.0) mL Urine Random Ambient 72 hrs; Refrigerated 2 weeks; Frozen 2 months		
Collection Instructions	Do not use any preservatives or additives		
Clinical Utility	Confirmation of screen-positive results		
Schedule	Tuesday, Friday		
Turnaround Time	1-5 days		
CPT Code	83925x2		
Notes	This panel includes Hydrocodone and Hydromorphone. Cutoff = 100 ng/mL		

4492UR Hydromorphone Urine AccuQuant®
(effective 08/16/05)

Component	Method	Reference Range	Units
Hydromorphone Urine	LC/MS-MS	<100	ng/mL
Specimen/Stability	10.0 (5.0) mL Urine Random Ambient 72 hrs; Refrigerated 2 weeks; Frozen 2 months		
Collection Instructions	Do not use any preservatives or additives		
Clinical Utility	Confirmation of screen-positive results		
Schedule	Tuesday, Friday		
Turnaround Time	1-5 days		
CPT Code	83925		
Notes	Cutoff = 100 ng/mL		

4494UR 6-Monoacetylmorphine (6-MAM) Urine AccuQuant®
(effective 08/16/05)

Component	Method	Reference Range	Units
6-Monoacetylmorphine	LC/MS-MS	<4.0	ng/mL

Specimen/Stability	10.0 (5.0) mL Urine, Random
	Ambient 5 days; Refrigerated 7days; Frozen 2 months
Collection Notes	Do not use any preservatives or additives
Clinical Utility	6-Monoacetylmorphine (6-MAM or 6-AM) is a metabolite of heroin. Heroin itself is not detected, due to its rapid conversion (T1/2 < 6 min) to 6-acetylmorphine and further to morphine (T1/2 <40 min). Both 6-MAM and morphine have euphoric effects. 6-MAM is rapidly eliminated and excreted into the urine; the "detection window" is <24 hrs. Therefore, 6-MAM-negative urine does not exclude exposure to heroin, but its presence confirms it.
Schedule	Wednesday, Saturday
Turnaround Time	1-5 days
CPT Code	83925
Notes	Cutoff= 4 ng/mL

1026 Myasthenia Gravis Evaluation PLUS
(effective 07/26/05)

Component	Method	Reference Range	Units
AChR Binding Autoabs	RIA	<0.25	nmol/L
AChR Blocking Autoabs	RIA	<15	%
AChR Modulating Autoabs	RIA	<20	%
Striational Autoabs	IFA	<1:40	titer

Specimen/Stability	4.0 (2.0) mL Serum
	Ambient 7 days; Refrigerated 2 weeks; Frozen 2 months
Collection Instructions	Do not use any preservatives or additives
Clinical Utility	Myasthenia gravis (MG), the most common neuromuscular transmission disorder, is an antibody-mediated autoimmune disease that stems from a loss of acetylcholine receptors (AChR) at neuromuscular junctions. AChR autoantibodies are diagnostic of MG, and are found in 85-90% of MG patients. AChR binding autoantibodies are present most frequently in MG and provide the most reliable information for diagnostic screening. A small portion of patients with early onset or ocular restricted MG may only have AChR modulating autoantibodies; thus, if AChR binding autoantibodies are absent in a patient with weakness or ocular symptoms consistent with MG, AChR modulating autoantibodies should be considered. AChR blocking autoantibodies are directed against the neurotransmitter-binding site and are the only AChR autoantibody in about 1% of MG patients. Striational autoantibodies are found in 80% to 100% of patients with myasthenia gravis and thymoma.
Schedule	Wednesday
Turnaround Time	2-9 days
CPT Code	84238x3, 86256

4185UR Opiates Confirmation Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
Codeine	LC/MS-MS	<100	ng/mL
Dihydrocodeine	LC/MS-MS	<100	ng/mL
Ethylmorphine	LC/MS-MS	<100	ng/mL
Hydrocodone	LC/MS-MS	<100	ng/mL
Hydromorphone	LC/MS-MS	<100	ng/mL
Morphine	LC/MS-MS	<100	ng/mL
Norcodeine	LC/MS-MS	<100	ng/mL
Normorphine	LC/MS-MS	<100	ng/mL
Oxycodone	LC/MS-MS	<100	ng/mL

Specimen/Stability	10 (5.0) mL Urine Random
	Ambient 72 hrs; Refrigerated 2 weeks; Frozen 2 months
Collection Instructions	Do not use any preservatives or additives
Clinical Utility	Confirmation of screen-positive results
Schedule	Tuesday, Friday
Turnaround Time	1-5 days
CPT Code	83925x9
Notes	This panel includes Codeine, Dihydrocodeine, Ethylmorphine, Hydrocodone, Hydromorphone, Morphine, Norcodeine, Normorphine, Oxycodone. Cutoff =100 ng/mL

4186UR Opiates Confirmation w/6-MAM Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
6-Monoacetylmorphine	LC/MS-MS	<4	ng/mL
Codeine	LC/MS-MS	<100	ng/mL
Dihydrocodeine	LC/MS-MS	<100	ng/mL
Ethylmorphine	LC/MS-MS	<100	ng/mL
Hydrocodone	LC/MS-MS	<100	ng/mL
Hydromorphone	LC/MS-MS	<100	ng/mL
Morphine	LC/MS-MS	<100	ng/mL
Norcodeine	LC/MS-MS	<100	ng/mL
Normorphine	LC/MS-MS	<100	ng/mL
Oxycodone	LC/MS-MS	<100	ng/mL

Specimen/Stability	10 (7.0) mL Urine Random Ambient 72 hrs; Refrigerated 7 days; Frozen 2 months
Collection Instructions	Do not use any preservatives or additives
Clinical Utility	Confirmation of screen-positive results
Schedule	Tuesday, Friday
Turnaround Time	2-6 days
CPT Code	83925x10
Notes	This panel includes Codeine, Dihydrocodeine, Ethylmorphine, Hydrocodone, Hydromorphone, Morphine, Norcodeine, Normorphine, Oxycodone. Cutoff= 100 ng/mL. It also includes 6-Monoacetylmorphine (6-MAM). Cutoff = 4 ng/mL.

4187UR Opiates Confirmation (Morphine & Codeine) Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
Codeine	LC/MS-MS	<100	ng/mL
Morphine	LC/MS-MS	<100	ng/mL

Specimen/Stability	10 (5.0) mL Urine Random Ambient 72 hrs; Refrigerated 2 weeks; Frozen 2 months
Collection Instructions	Do not use any preservatives or additives
Clinical Utility	Confirmation of screen-positive results
Schedule	Tuesday, Friday
Turnaround Time	1-5 days
CPT Code	83925x2
Notes	This panel includes Codeine and Morphine only. Cutoff = 100 ng/mL.

4180U Porphyrins, Fractionated with Porphobilinogen 24hr Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
Porphobilinogen 24 hr	Spectrophotometry	<3.0	mg/24hr
Uroporphyrin 24 hr	HPLC	<30.0	ug/24hr
Heptacarboxyporphyrin 24 hr	HPLC	<7.0	ug/24hr
Hexacarboxyporphyrin 24 hr	HPLC	<1.1	ug/24hr
Pentacarboxyporphyrin 24 hr	HPLC	<4.0	ug/24hr
Coproporphyrin I 24 hr	HPLC	<50.0	ug/24hr
Coproporphyrin III 24 hr	HPLC	<65.0	ug/24hr
Total Porphyrins 24 hr	HPLC	10.0 – 150.0	ug/24hr

Specimen/Stability	4.5 (2.0) mL 24 hr Urine Frozen 2 months
Collection Instructions	Split into 2 plastic vials before freezing. Protect from light; wrap specimen tube in foil or use amber tube. Specify total urine volume. Ship frozen.
Clinical Utility	Useful in the diagnosis of porphyrias
Schedule	Tuesday, Friday
Turnaround Time	2-5 days
CPT Code	84110, 84120
Notes	For Porphyrins, Fractionated 24hr Urine (without Porphobilinogen) use test code #4182U.

4182U Porphyrins, Fractionated 24hr Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
Uroporphyrin 24 hr	HPLC	<30.0	ug/24hr
Heptacarboxyporphyrin 24 hr	HPLC	<7.0	ug/24hr
Hexacarboxyporphyrin 24 hr	HPLC	<1.1	ug/24hr
Pentacarboxyporphyrin 24 hr	HPLC	<4.0	ug/24hr
Coproporphyrin I 24 hr	HPLC	<50.0	ug/24hr
Coproporphyrin III 24 hr	HPLC	<65.0	ug/24hr
Total Porphyrins 24 hr	HPLC	10.0 – 150.0	ug/24hr

Specimen/Stability	4.5 (2.0) mL 24 hr Urine Frozen 2 months
Collection Instructions	Split into 2 plastic vials before freezing. Protect from light; wrap specimen tube in foil or use amber tube. Specify total urine volume. Ship frozen.
Clinical Utility	Useful in the diagnosis of porphyrias
Schedule	Tuesday, Friday
Turnaround Time	2-5 days
CPT Code	84120
Notes	For Porphyrins, Fractionated on random urine (without Porphobilinogen) use test code #4182UR.

4182UR Porphyrins, Fractionated Random Urine
(effective 08/16/05)

Component	Method	Reference Range	Units
Uroporphyrin Random Urine	HPLC	<22.0	ug/g creatinine
Heptacarboxyporphyrin Random Urine	HPLC	<4.7	ug/g creatinine
Hexacarboxyporphyrin Random Urine	HPLC	<0.8	ug/g creatinine
Pentacarboxyporphyrin Random Urine	HPLC	<2.8	ug/g creatinine
Coproporphyrin I Random Urine	HPLC	<35.0	ug/g creatinine
Coproporphyrin III Random Urine	HPLC	<45.5	ug/g creatinine
Total Porphyrins Random Urine	HPLC	7.0 – 110.0	ug/g creatinine

Specimen/Stability	3.0 (1.5) mL Urine Random Frozen 2 months
Collection Instructions	Split into 2 plastic vials before freezing. Protect from light; wrap specimen tube in foil or use amber tube. Ship frozen.
Clinical Utility	Useful in the diagnosis of porphyrias
Schedule	Tuesday, Friday
Turnaround Time	1-5 days
CPT Code	84120

3553 S-100B Serum AccuQuant®
(effective 08/16/05)

Component	Method	Reference Range	Units
S-100B	CL	<0.09	ug/L

Specimen/Stability	1.0 (0.5) mL Serum Refrigerated 72 hrs; Frozen 2 months
Collection Instructions	EDTA plasma samples are not acceptable. Icteric, lipemic or hemolyzed samples are not suitable for analysis.
Clinical Utility	Determination of S-100B in serum is clinically useful for prognosis and treatment monitoring of patients diagnosed with malignant melanoma. Furthermore, elevated serum and CSF levels of S-100B can be useful in the management of patients with brain damage from, for example, traumatic head injury, perinatal asphyxia, cardiac arrest, cardiac surgery or stroke.
Schedule	Tuesday, Friday
Turnaround Time	1-5 days
CPT Code	83520

3553C S-100B CSF AccuQuant®
(effective 08/16/05)

Component	Method	Reference Range	Units
S-100B	CL	0.38 – 2.87	ug/L

Specimen/Stability	1.0 (0.5) mL CSF Refrigerated 72 hrs; Frozen 2 months
Collection Instructions	Blood-contaminated samples are not suitable for analysis.
Clinical Utility	Elevated serum and CSF levels of S-100B can be useful in the management of patients with brain damage from, for example, traumatic head injury, perinatal asphyxia, cardiac arrest, cardiac surgery or stroke.
Schedule	Tuesday, Friday
Turnaround Time	1-5 days
CPT Code	83520

3249 Testosterone, Free Dialysis with Total Testosterone
(effective 08/16/05)

Component	Method	Reference Range	Units
Testosterone, Total [RIA]	RIA	see below	ng/dL

Age	Males	Females
0 - 11 M	<6	<5
1 Y - 5 Y	2-25	2-10
6 Y - 9 Y	3-30	2-20
10 Y - 11 Y	5-50	5-25
12 Y - 14 Y	10-572	10-40
15 Y - 17 Y	220-800	5-40
>17 Y	241-827	14-76

Testosterone, % Free Dialysis — Equilibrium Dialysis — see below — %

Age	Males	Females
0 - 11 M	0.4-1.0	0.5-1.0
1 Y - 5 Y	0.4-0.9	0.4-0.9
6 Y - 10 Y	0.4-0.9	0.4-0.9
11 Y - 15 Y	0.4-3.2	0.5-1.4
>15 Y	1.5-3.2	0.8-1.4
Pregnant		0.2-0.5

Testosterone, Free Dialysis — CALC — see below — pg/mL

Age	Males	Females
0 - 11 M	0.4-31	0.1-2.5
1 Y - 5 Y	0.2-0.6	0.2-0.6
6 Y - 10 Y	0.1-0.9	0.1-0.9
11 Y - 15 Y	0.4-110	0.2-6.2
>15 Y	52-280	1.1-6.3
Pregnant		0.2-3.2

Specimen/Stability	5 (1.5) mL Serum Ambient 72 hrs; Refrigerated 72 hrs; Frozen 2 months
Clinical Utility	Free testosterone by dialysis is recommended for pediatric and female patients as well as males with low testosterone. For most males, depending on the clinical circumstances, Testosterone Free by analog method (test code #3247) can be used.
Schedule	Monday, Wednesday, Friday
Turnaround Time	2-5 days
CPT Code	84402, 84403

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
1514	08/16/05	Alpha-1-Antitrypsin PhenotypR™	Name Alpha-1-Antitrypsin PhenotypR™ w/o total AAT	
1901	08/16/05	Apolipoprotein A-1	Method Turbidimetry Reference Range 60-170 mg/dL Collection Instructions Lipemic, icteric, or hemolyzed samples are not suitable for analysis	1900 Apolipoprotein Evaluation

Test Code	Effective Date	Test Name	Specific Change	Also Affected
1903	08/16/05	Apolipoprotein B	Method Turbidimetry Reference Range 40-130 mg/dL Collection Instructions Lipemic, icteric or hemolyzed samples are not suitable for analysis	1900 Apolipoprotein Evaluation
4500I	07/09/05	Cadmium Exposure Panel OSHA – Whole Blood and Urine Random	Component Name B2-Microglobulin/Creatinine Ratio	4500URI Cadmium Exposure Panel OSHA - Urine Random
1501	08/16/05	Complement C3	Method Turbidimetry Reference Range 82-170 mg/dL Stability Ambient 72 hrs; Refrigerated 7 days; Frozen 2 months Collection Instructions Lipemic, icteric or hemolyzed samples are not suitable for analysis	1500 Complement C3 and C4 1000 ANA*lyzer*® 1005 ANA*lyzer*® *w/o* ANA 1006 ANA*lyzer*® w/o RheumFactor 1004 Rheumatoid Eval 1126 ANA, Profile #2 1040 Immune Complex Detector 1020 Complement Eval 1021 Complement Eval plus CH50 1094 Lupus Activity Reporter 5023 Lupus Renal Eval 1726 Rapidly Prog Glomeruloneph
1504	08/16/05	Complement C4	Method Turbidimetry Reference Range 16-70 mg/dL Stability Ambient 72 hrs; Refrigerated 7 days; Frozen 2 months Collection Instructions Lipemic, icteric or hemolyzed samples are not suitable for analysis	1500 Complement C3 and C4 1000 ANA*lyzer*® 1005 ANA*lyzer*® w/o ANA 1006 ANA*lyzer*® w/o RheumFactor 1004 Rheumatoid Eval 1126 ANA, Profile #2 1040 Immune Complex Detector 1020 Complement Eval 1021 Complement Eval plus CH50 1094 Lupus Activity Reporter 5023 Lupus Renal Eval 1726 Rapidly Prog Glomeruloneph
1535	08/16/05	C-Reactive Protein, Inflammation	Method Turbidimetry Collection Instructions Lipemic, icteric or hemolyzed samples are not suitable for analysis	1014 Rheum Arthritis Comprehensive
9430	08/16/05	Cytomegalovirus DNA UltraQuant®	Alternate Specimens Bronchoalveolar Lavage, Tissue, Other (sterile container) are no longer acceptable samples for this assay; for those samples, use CMV DNA DetectR™ (test code # 7575)	9430SR Cytomegalovirus DNA UltraQuant® with serial reporting
7584	08/16/05	Epstein-Barr Virus DNA UltraQuant®	Alternate Specimens Bronchoalveolar Lavage, Tissue, Other (sterile container) are no longer acceptable samples for this assay; for those samples, use EBV DNA DetectR™ (test code #7583)	
7758	6/28/05	Hepatitis A, B & C Virus Post Exposure Panel	Specimen Volume 4.0 (3.0) mL	7756 Hepatitis A & B Acute Eval 7757 Hepatitis Acute Profile
7581	08/16/05	Herpes Simplex Virus DNA DetectR™	Alternate Specimen/Stability ThinPrep Vial 1.5 (0.5) mL; Ambient 21 days; Refrigerated 21 days Use ThinPrep Pap Test Collection Kit and endocervical broom/brush Tripath SurePath Vial 1.5 (0.5) mL; Ambient 28 days; Refrigerated 6 months Use Tripath SurePath Test Collection Kit for cervical ample collection. Cervical/vaginal swab in Cytyc PreserveCyt solution or Tripath CytoRich solution 1.5 (0.5) mL; Ambient 21 days; Refrigerated 21 days. Collection Instructions Cytologic specimens should be collected according to the instructions provided with the ThinPrep or SurePath kits for cervical samples. M4 Transport Media/Swab; Ambient 7 days Tissue 0.2 (0.1) g tissue; frozen 2 months Collection Instructions Swab of Vesicle Fluid or Scrapings should be sent in M4 transport media. Ship frozen tissue on dry ice.	

Test Code	Effective Date	Test Name	Specific Change	Also Affected
9474	08/16/05	Herpes Simplex Virus DNA UltraQuant®	Alternate Specimens Culturette/Swab, M4 Transport Media Swab and Tissue are no longer acceptable samples for this assay; for those samples, use Herpes Simplex Virus DNA DetectR™ (test code #7581)	
4196	08/16/05	Lamotrigine	CPT Code From 80299 to 82491	
2422	08/16/05	Legionella pneumophila Ag Detection	Alternate Specimens Urine is an acceptable alternate specimen. Note Although *Legionella* is detectable in urine by DFA, a more sensitive assay is #9501 *Legionella pneumophila* Ag, Urine by EIA.	
8260	08/16/05	Parvovirus B19 DNA UltraQuant®	Alternate Specimens Tissue fixed in formalin or saline or tissue embedded in paraffin are no longer acceptable samples for this assay; for those samples, use Parvovirus B19 DNA DetectR™ (test code #8266)	
8266	08/02/05	Parvovirus B19 DetectR™	Name Parvovirus B19 DNA DetectR™	
1540	08/16/05	Rheumatoid Factor	Method Turbidimetry Reference Range <60 IU/mL	1540F Rheumatoid Factor Fluid 1000 ANA*lyzer*® 1005 ANA*lyzer*® without ANA 1126 ANA Profile #2 1010 Arthritis Evaluation 1014 Rheum Arthritis Comprehensive
8760	08/16/05	Varicella-zoster Virus DNA UltraQuant®	Alternate Specimens Tissue is no longer an acceptable sample for this assay; for those samples, use 7585 VZV Virus DNA DetectR™ (test code #7585)	
3275	08/16/05	Zinc Protoporphyrin	Alternate Specimens EDTA Whole Blood in microtainer should be foil wrapped	

Referral Testing Changes

Discontinue Referral Test S50097 and use #1614 Alpha-Antitrypsin PhenotypR™
Discontinue Referral Test S50436 and use #7230 Connexin 26 GenotypR™
Discontinue Referral Test S48559 and use #4180U Porphyrins, Fractionated with Porphobilinogen24hr Urine
Discontinue Referral Test S48558 and use #4182UR Porphyrins, Fractionated Random Urine
Discontinue Referral Test S50360 and use #9617U Bladder Tumor Antigen, Urine
Discontinue Referral Test S48894 and use #4185UR Opiates Confirmation, Urine
Discontinue Referral Test S50864 and use #4186UR Opiates Confirmation w/6-MAM Urine
Discontinue Referral Test S50865 and use #4187UR Opiates Confirmation (Morphine & Codeine) Urine
Discontinue Referral Test S50373 and use #1078 Celiac Disease GenotypR™
Discontinue Referral Test S50045 and use #1364 HLA-B*27 GenotypR™

Please call Client Services at 800-421-4449 or visit our website at www.specialtylabs.com for more information.

SPECIALTY LABORATORIES
27027 Tourney Road 800•421•7110
Valencia, CA 91355 www.specialtylabs.com

DATE: **August 2005**
SUBJECT: **Fee for Attempted Assay Performance That Does Not Generate A Reportable Result**

Effective September 1, 2005 Specialty Laboratories will initiate a policy consistent with that of other laboratories in which a fee will be charged for assays and panels that require significant testing and labor but do not yield a reportable result due to factors beyond the laboratory's control. This policy change will enable us to maintain the overall fees for the designated assays at a manageable level. For example, on GenotypR™ assays *Specialty* performs the testing at least twice before concluding that no result is obtainable, generally due to insufficient viral load. For a complete list of tests affected by this new policy, see below. Alternatively, you may call Client Services at 800-421-4449 or visit our Web site at www.specialtylabs.com.

Assay Attempt Without Result – Affected Tests

Test Code	Test Name	Test Code	Test Name
1518	Alpha-1-Antitrypsin Deficiency Fetal Study	8132	Hepatitis B Virus Drug Resistance DetectR™
1515	Alpha-1-Antitrypsin GenotypR™	8134	Hepatitis B Virus GenotypR™
5342	BCR/ABL UltraQuant® Major 210 KD Transcript Bone Marrow	7473	Hepatitis C Virus SubtypR®
5352	BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood	7420	HIV Phenoscript™
5344	BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow	7420NY	HIV Phenoscript New York
5354	BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood	7480	HIV-1 GenotypR™ Plus (Rev Trans & Prot Inhib)
5836	Breast Cancer HER2/*neu* [By FISH Only]	7480NY	HIV-1 GenotypR™ Plus (Rev Trans & Prot Inhib) New York
5822	Chromosome Analysis Amniotic Fluid	1376	HLA-A DetectR™
5818	Chromosome Analysis: Products of Conception/Skin Biopsies	1368	HLA-A, B, C DetectR™
5355	Cystic Fibrosis 40 GenotypR™: Carrier Study	1369	HLA-A, B, C, DR DetectR™
5356	Cystic Fibrosis 70 GenotypR™: Carrier Study	1377	HLA-B DetectR™
5357	Cystic Fibrosis 70 GenotypR™: Diagnostic Study	1378	HLA-C DetectR™
5358	Cystic Fibrosis 70 GenotypR™: Fetal Study	1379	HLA-DR DetectR™
5814	Cytogenetics, Congenital Disorders	5365	Maternal Cell Contamination Detection Fetal/Cord Blood
5800	Cytogenetics, Hematologic and Neoplastic Disorders	4559	MTHFR A1298c Mutation
5371	Factor II (Prothrombin) GenotypR™	4558	MTHFR GenotypR™ (C677t Mutation)
1966	Factor V [Leiden] GenotypR™	4560	MTHFR GenotypR™ Reflex to A1298c Mutation
5363	Fragile X Fetal Study	1705	Narcolepsy EvaluatR™
5362	Fragile X GenotypR™	5375	Plasminogen Activator Inhibitor (PAI-1) GenotypR™
5369	Hemochromatosis GenotypR™	4555	Thrombotic Risk AssessR™ for Obstetric Complications
8144	Hepatitis B Virus Core/Precore Mutant DetectR™	5353	TPMT GenotypR™